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True device compliance: the need to consider both competence and contrivance

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Summary Inability to use inhalers effectively is known to adversely affect the delivery of drug. It is assumed that increasing competence to use inhalers will lead to improved drug delivery. However many subjects appear competent (are able to use a device effectively) but contrive to use the device in a sub-optimal way in routine use. This study aimed to explore levels of True device compliance, that is the extent to which devices are used effectively in routine use, and to explore the influences of age and device on this parameter. The ability of 53 asthmatic patients aged 1–88 years to use their corticosteroid inhaler was assessed by a single investigator. In addition information regarding patient behaviour in routine practice was explored in a structured interview. True device compliance was defined to occur when a subject was rated competent and did not report contrivance. Competence was related to device type. All subjects using a holding chamber[pMDI + HC] ($N = 21$) or breath activated inhaler ($N = 5$) could demonstrate an adequate technique compared with only 9 (47%) of those prescribed a pMDI. However only 4 (19%) prescribed a pMDI + HC were true device compliant with the majority regularly using the pMDI alone while (42%) of those prescribed a pMDI were True device compliant. Since 82% of patients over 65 were prescribed pMDI alone, and 92% of patients up to 5 years were prescribed pMDI + HC, True device compliance was low among both groups. Only 33% of patients over 65 prescribed pMDIs were able to use them competently. Lack of competence, particularly in the elderly, and contrivance, particularly common amongst those using holding chambers, are two important but independent impediments to effective inhaled therapy.

Introduction

The introduction of an effective inhaled corticosteroid (ICS) almost 30 years ago[1] transformed the management of asthma. The use of these agents results in a significant reduction in morbidity with reduced daytime and night time symptoms, improved exercise tolerance and, importantly, fewer and less severe exacerbations.[2,3] In addition they have probably led to a fall in mortality.[4]

However to be effective these drugs must be regularly delivered to the lungs via the airways in sufficient quantities to have a therapeutic effect and failure to do so results in increased morbidity.[5–7]

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In order to achieve effective delivery a number of steps are required. The patients must first be provided with a device that generates aerosolised drug with the majority of drug particles having a mass median aerosolised diameter of 1–5 μm as particles in this size range are most likely to deposit in the lungs.[8] The patient then must both use their inhalers regularly [comply with or adhere to a suggested treatment regimen] and use the device in a specific manner to optimise drug delivery. Failure to use an inhaler optimally [poor device compliance] may result in very low levels of drug delivery to the lungs or indeed may result in complete failure of drug delivery[9] even when the patient adheres to the suggested regimen. Failure to use a device effectively may be due to an inability to use a device effectively [lack of competence] or to a deliberate use of the device in manner that is sub-optimal [contrivance]. In the later situation the patient can demonstrate effective use of the device but chooses to use it in a different, inefficient, manner.

It is recognised that poor regimen compliance is common in all diseases and does not appear to be related to age, sex, disease, educational attainment, understanding of disease or disease severity.[10] Unfortunately there has been little evidence that health care professionals can significantly influence regimen compliance with the possible exception of interventions immediately following an acute episode such as a hospital admission. However, as noted above, even when patients comply or adhere to a treatment regime they frequently fail to derive significant therapeutic benefit due to poor device compliance. There have been many studies indicating that many patients and health care professionals do not possess the competence to use devices effectively.[11–20] Usually this is because they have not been taught effectively. In order to address this problem patient education programmes recommend training patients in correct inhaler technique and where necessary transferring patients to more appropriate device. Implicit in this approach is a belief that improved competence will result in improved device compliance leading to improved therapeutic outcomes. However there are few studies supporting this assumption. Anecdotal reports suggest that many patients who are able to demonstrate competence in the clinic setting contrive to use the device ineffectually in routine practice. Obvious examples are not using a holding chamber when prescribed one for use with a pMDI and stopping inhaling once a breath actuated inhaler has been triggered. This form of behaviour in which a subject knows how to perform an action effectively but chooses or contrives to use a different ineffectual technique is known as contrivance and is observed in many setting. For example, doctors know why they should wash their hands when moving from patient to patient on a ward round, can demonstrate competence in doing so in front of the infection control nurse but all to often contrive not to do so when they feel they are not being observed.[21]

While there are many previous studies assessing patient's competence we are not aware of any studies that have specifically sought to explore the possibility that significant numbers of patients may modify their inhaler technique in routine practice when not being observed by a health care professional. This study aimed to explore the possible influences of age and device on the ability of patients to use inhalers effectively. In addition we aimed to explore whether patients routinely modified their inhaler technique outside the clinic setting.

Methods

A single individual from outside the respiratory teams (VKB) interviewed a total of 53 asthmatic subjects aged 1–88 years recruited from asthma clinics and inpatients at the Sheffield's Children's and Northern General Hospitals. Patients and/or parents were reassured that their responses would remain confidential. All patients were routinely taking inhaled corticosteroids for chronic asthma.

Patients were asked to demonstrate how they used their ICS inhaler and their ability to use the device effectively was assessed by the investigator. Inhaler technique was assessed as using a standardised checklist (see Table 1) based on standard recommendations. Patients were deemed to be competent i.e. to have an adequate technique if they (1) did not make a major error such as failing to prime a DPI or have significant hand breath coordination errors when using a pMDI or (2) did not make more than one more minor error such as failing to shake a pMDI before use or omit a breath hold.

Subjects were subsequently asked if this was the technique used at home or whether they modified their technique in routine use. If they did modify their technique they were asked to explain why. Patients were defined as using Contrivance if they were able to demonstrate that they were competent to use their device effectively but reported that they frequently altered their inhaler technique when outside the clinic setting.

Table 1

MDI
Remove mouthpiece cap
Shake device
Hold inhaler upright
Breath out gently
Close lips around mouthpiece
Breath in slowly over several seconds
Actuate canister as patient starts to inhale
Hold breath for 10 s
pMDI with holding chamber
As above with addition of
Assemble pMDI and holding chamber correctly
Single actuation of canister followed by
1 slow inspiratory breath with breath hold [for older subjects]
or
breathing in and out of holding chamber for 10 s
Dry powder inhaler
Remove cap
Prime device effectively
Exhale to residual volume
Place mouthpiece between lip
Inhale forcefully and deeply
Hold breath for as long as comfortable

Patients were assessed as True device compliant if they were competent and if they did not report modifying their technique during routine use outside the clinic.

Having identified contrivance as a significant problem amongst children using holding chambers a discussion regarding the impact of modifying inhaler technique outside the clinic setting was incorporated into the routine assessment during clinic visits. Two years after the initial study we assessed the impact of this on levels of contrivance again using an outside investigator (HG) who interviewed 30 children and their carers. All the children were using pMDI and holding chamber to deliver their ICS. Sixteen were aged 2–6 years, 14 aged 7–16 years. In addition being asking about their use of the spacer they were also asked about their adherence to the recommended treatment regime.

The study was approved by the local Research Ethics Committee.

Results

Details regarding patient ages, devices used, numbers with adequate technique and overall device compliance are shown in Table 2. Eighteen of 27 children aged 1–15 years and 3 of 26 adults had been prescribed a holding chamber.

Competence was found to be significantly related to age and was worse in the elderly than the other age groups. Of 9 patients over 65 years prescribed a pMDI only 1 subject had a completely adequate technique (two more made minor errors and were classed as competent). By comparison, amongst those aged 16–65 years and prescribed MDIs, 7 (70%) were classed as competent. The three most dramatic examples of lack of competence were manifest by two patients who sprayed the pMDI on their chest and one who failed to remove the cap. The most common error was poor co-ordination between actuating the device and inhaling. One child using a Turbohaler failed to prime the device. Less important errors included omitting the breath hold and failing to shake the canister before use. The commonest minor error with the spacer was failing to shake the pMDI. Despite these examples of poor competence all subjects believe that their technique was correct.

Contrivance was very common particularly among those prescribed a holding chamber. One-hundred percent of all subjects using a holding chamber were competent (could demonstrate a good or adequate technique). However 81% of these, including the parents of 10 of 11 children under 5 years of age, stated that they frequently did not use the holding chamber to administer ICS. The commonest reason given for not using the holding chamber was that the parent or patient was 'too busy' or in a rush. Four subjects using a pMDI and the one using a breath actuated pMDI described deliberately omitted the breath hold because 'it took too long'.

True device compliance was lowest in the youngest [due to contrivance] and oldest [due to lack of competence]age groups, but the effect of aged did not reach statistical significance.

In the follow up study limited to children using pMDIs and holding chambers only 2 of 30 (7%) patients/parents indicated that they regularly omitted the holding chamber and a further 2 (7%) used the pMDI alone occasionally. All four subjects were older than 7 years of age. Sixty six percent of all the children reported missing at least one dose a week and there did not appear to be any significant trends in self reported levels of adherence across the age spectrum. However self reported levels of adherence were much lower in the 4 subjects reporting occasional or frequent use of the pMDI without a spacer. These subjects reported that they were not convinced that their treatment was helping them.

Table 2

Age range (yrs)	Number	Devices used		*N* (%) competent (adequate technique)	*N* [%] True device compliant
1–5	12	pMDI + HC	11	11 (100)	1 (9
		DPI	1	1 (100)	1 (100)
		Total		12 (100)	2 (17)
7–15	15	pMDI + HC	7	7 (100)	2 (29)
		DPI	4	2 (50)	2 (50)
		BA pMDI	4	4 (100)	3 (75)
		Total		13 (86)	7 (47)
16–64	15	pMDI	10	7 (70)	5 (50)
		pMDI + HC	2	2 (100)	1 (50)
		DPI	2	2 (100)	2 (100)
		BA pMDI	1	1 (100)	1 (100)
		Total		12 (80)	9 (60)
65–88	11	pMDI	9	3 (33)	3 (33)
		pMDI + HC	1	1 (100)	0 (0)
		DPI	1	1 (100)	1 (100)
				5 (46)	4 (36)

Device compliance = % subject who were competent and did not modify their technique regularly.
BA pMDI: Breath actuated pMDI.

Discussion

This study highlights for the first time the need to consider three independent factors when trying to assess whether a patient is using an inhaler device effectively. It is well known that poor regimen compliance [adherence] can have a major impact on therapeutic outcomes. It has also been well established that lack of competence will result in ineffectual drug delivery to the lungs but no previous study has highlighted the need to consider whether contrivance may also be adversely affecting therapeutic outcomes. True device compliance involves both being competent and using the device effectively when not being observed [not contriving to use an ineffective technique]. The high levels of contrivance identified in this study, particularly amongst those using holding chambers, would indicate that that sub-optimal responses to therapy will be observed in many patients even when they are compliant with a treatment regimen and can demonstrate a good inhaler technique [are competent] when seen in the clinic.

The low levels of competence amongst the elderly using portable inhalers appears to be the major impediment to effective therapy amongst those in this age group. This was not a surprise since previous studies have also highlighted the low levels of competence with inhalers amongst the elderly.[12–15] The lack of competence amongst many elderly patients reflects the fact that current devices are not intuitive to use and require considerable cognitive ability to use effectively. Cognitive issues are particularly a problem in this age group.[12–15,22] The high level of pMDI use in this age group is also likely to have contributed to the low levels of competence. In contrast to the results presented by the Kamps et al.[20] we found that most children attending the clinic were competent to use their inhalers effectively and we believe this reflects the effective intervention of our respiratory nurses.

Despite the high levels of competence we found that true device compliance amongst children included in the principle study was similar to that in the elderly due to high levels of contrivance. Overall 81% of all subjects using a holding chamber reported regularly using the pMDI alone and this behaviour was seen in all age groups. Although all parents of pre-school children were able to use a holding chamber adequately, the majority described regularly actuating the pMDI directly into the child's mouth when administering inhaled corticosteroids despite knowing the reasons for using the holding chamber. These results are very similar to those reported in a study involving adult subjects in whom the rate of 'spacer disuse' was reported as 67%.[23] The perceived 'inconvenience' of using the spacer out weighed all the information provided by health care professionals. In clinical practice contrivance is also observed with other devices such intentionally omitting a breath hold with a pMDI and stopping inhaling once a breath actuated pMDI's has fired. Such finding calls into

question the uncritical recommendations that all subjects should be prescribed a pMDI and holding chamber.[24] Fortunately some guidelines have taken into account the influence of individual patient behaviour on outcomes and while recommending holding chambers recognise that other devices such as dry powder inhalers may be more appropriate for individual patients.[25,26]

Contrivance is common in many settings. Those with a driving licence know that it is safer to drive within the speed limit and will demonstrate this skill during a driving test. However many will frequently contrive to drive in a dangerous manner because they are convinced that their driving techniques are such that they can ignore the advice of others. As noted above this pattern of behaviour is frequently observed amongst doctors who understand that hand washing can reduce the spread of infective organisms and can show that they have the competence to effectively wash their hands but time and again they contrive to examine patients without first washing their hands.[21,27]

Self reporting of modification of behaviour is likely to underestimate the true level of contrivance but we feel this may have been minimised by the use of a non-medical investigator from outside the clinical team and assurances that answers would remain confidential. Being aware of such behaviour is important in that it can then be addressed as part of the routine clinical consultation. The data from the follow up study suggests that levels of contrivance amongst children using holding chambers appeared to fall dramatically to only 14% of subjects once this type of behaviour was acknowledged and addressed in the clinic.

Contrivance may not only contribute to therapeutic failures but may also significantly alter the 'therapeutic index' of inhaled corticosteroids. Higher upper airways deposition due will result in an increased risk of local side effects such as hoarseness or candida infection. In addition the potential for systemic side effects of ICS such as beclomethasone, which have a relatively high systemic availability when swallowed,[28] may be increased. It is very likely that many children are on unnecessarily high prescribed doses of ICS to compensate for the poor delivery to the lungs when they contrive not to use their spacer. As a result, the dose of swallowed ICS will be significantly increased both because the patient actuates the pMDI directly into their mouth and because the dose has been increase to compensate for their poor technique.

Those involved in the management of asthmatic patients need to be aware that simply assessing a patient's competence in the clinic will significantly over estimate true device compliance. Many patients will contrive to misuse their inhalers even when they are competent with the device, particularly when using pMDIs with holding chambers. Patients and/or their carers should be asked about their use of the device in routine practice as well as being asked to demonstrate that they can use the device effectively.

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